



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 411573; **FILE SYMBOL No.:** 72500-EG; **PRODUCT NAME:** Diphacinone Technical;
DECISION No.: 477628; **PC Code(s):** 067701; **ACTION CODE:** R310; **FOOD Use:** Yes

DATE: August 8, 2013

SUBJECT: Product Chemistry Review of "Diphacinone Technical"

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DP BARCODE: 411573
DECISION No.: 477628
REGISTRATION NUMBER: 72500-EG
PRODUCT NAME: Diphacinone Technical
PC CODE: 067701
REGISTRANT: Scimetrics Ltd., Corporation
USE: Insecticide
FOOD USE: Yes [X] No []
MRID Numbers: 491020-01 to 491020-05

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INTRODUCTION:

Scimetrics Ltd Corporation has submitted an application for the registration of the proposed diphacinone Technical. The registrant has submitted a CSF for basic formulation (dated April 19, 2013). The proposed diphacinone is produced by [REDACTED] for Scimetrics with nominal concentration of 98.8% for the active ingredient. The proposed basic CSF is supported by the group A and group B product chemistry data submitted under MRID Nos. 491020-01 to 491020-05 and the product label. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 61282.1. TRB has been asked to evaluate and determine the acceptability of the proposed basic CSF (dated 04-19-2013), the supporting product chemistry data and substantial similarity to the cited product.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant has submitted a CSF for basic formulation (dated 04-19-2013). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 98.8% for AI concurs with the product label claim nominal concentration of 98.8% [MRID 491020-01].

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the Willowood Fomesafen technical [MRID No. 491020-01].

830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The diphacinone technical was produced by an integrated formulation system using chemical reaction batch process. [REDACTED] The details of the production process have been provided by the registrant [MRID No. 491020-01].

830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has listed [REDACTED] impurities with concentration of >0.1%. The registrant has provided the mechanisms of the formation of the all impurities identified in the 5 batch analysis [MRID No. 491020-01].

830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF satisfy the data requirements of 40CFR§158.345. The five lots of the test substance were analyzed to verify the concentration of diphacinone. The concentration of the AI in five lots ranged from 98.7% to 99.0%. The percent by weight of the impurity in diphacinone TGA1 ranged from [REDACTED]. The five lots were analyzed by validated analytical method (GL#82-66-6-9) which involved HPLC-UV (286 nm) technique to identify & quantify the active ingredient & the impurities. The study was conducted by Genesis Laboratories, Incorporation, Wellington, Co, USA [MRID No. 491020-02].

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The proposed certified limits for the active ingredient and for the impurities are based on the five batch analysis [MRID No. 491020-01].

830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The high performance liquid chromatography (HPLC) method utilizing reverse phase separation and UV detection (286 nm) was employed to determine the concentration of the active ingredient. The method was validated for linearity, reproducibility and recovery [MRID No. 491020-01].

2. The 830 series group B guideline data (physical-chemical properties) submitted satisfy the data requirements of 40CFR§158.310(e) [MRID Nos. 491020-03, 491202-04 & 491020-05].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for proposed Diphacinone Technical (produced by [REDACTED] to support the alternate CSF (dated 04-19-2013) and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A and group B are acceptable.
2. The proposed CSF for basic formulation (dated 04-19-2013) is acceptable. The nominal concentration of 98.8% concurs with the product label claim nominal concentration of 98.8%.
3. The proposed product with File Symbol No. 72500-EG was found to be substantially similar to the cited product with Reg. No. 12455-25 from the product chemistry point of view.
4. Since the technical was found to be incompatible with oxidizing agents, the registrant is required to add the following warning under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 411573; FILE SYMBOL No.: 72500-EG; PRODUCT NAME: Diphacinone Technical;
DECISION No.: 477628; PC Code(s): 067701; ACTION CODE: R310; FOOD Use: Yes

830.1550. Product identity & composition: (MRID No. 491020-01)

IUPAC: 2-(diphenylacetyl)indan-1,3-dione

CAS: 2-(diphenylacetyl)-1*H*-indene-1,3(2*H*)-dione

Reg. No.: 82-66-6

Formula: C₂₃H₁₆O₃

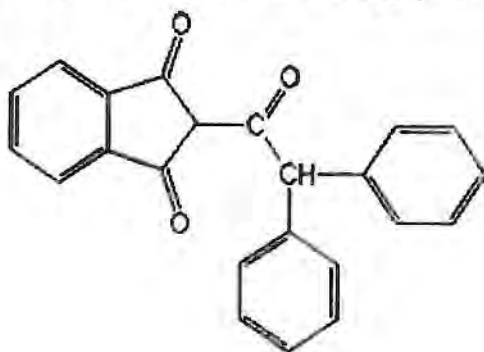
Activity: rodenticides (indandione rodenticides)

Notes: When this substance is used as a salt, its identity should be stated, for example diphacinone-sodium [42721-99-3].

The name "diphacin" is used in Turkey.

The name "diphenadione" is approved by the British Pharmacopoeia Commission.

Structure:



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Group A Data

Table 1. Manufacturing and Impurity Data Diphacinone Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	491020-01	A	Submitted basic CSF (dated 04-19-13) with NC of 98.8% for the AI.
830.1600	Description of materials used to produce the product	" "	A	Submitted the MSDS's for all the starting materials used in the synthesis of diphacinone technical at the new site [REDACTED]
830.1620	Description of production process	" "	A	Produced by the [REDACTED] The manufacturing process has been described in detail. The quality assurance procedures adopted in each step of the process have been included.
830.1670	Discussion of formation of impurities	" "	A	Impurities discussed and identified. The discussions on the mechanisms of the formation of all impurities listed on the CSF have been provided. [REDACTED] impurities have been listed in the CSF.
830.1700	Preliminary analysis	491020-02	A	The five batch analysis of the diphacinone technical was conducted to determine the contents of the active ingredient and the impurities. The HPLC-UV (286 nm) method was used the identification of the AI & impurities. The analytical methods were validated for linearity, accuracy, precision, LOQ and LOD.
830.1750	Certified limits	491020-01	A	The proposed limits for the AI and the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	491020-01	A	High performance liquid chromatography with UV detection (286 nm) was used for the identification of the active ingredient. The method was validated for linearity, precision and accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

Manufacturing process information may be entitled to confidential treatment

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830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of: Diphacinone Technical TGA1/MUP					
GLN	Requirement	MRID	Status	Result or Deficiency	
830.6302	Color	491020-03	A	Yellow	
830.6303	Physical state	" "	A	Solid Powder	
830.6304	Odor	" "	A	Odorless	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	" "	A	Not sensitive to elevated temperature (54°C) and not specifically sensitive to common metals and their salts (ionic) during 14 days test.	
830.6314	Oxidation/reduction: chemical incompatibility	" "	A	Compatible with water, 0.1 M aqueous sulfuric acid, Fe powder, and mono-ammonium phosphate basic. But was incompatible with household bleach and slightly basic liquids.	
830.6315	Flammability	" "	N A		
	Exploability		NA		
830.6317	830.6316	491020-04	A	The test substance was found to be stable and did not show any degradation when stored for one year in commercial containers under warehouse conditions. No physical-chemical changes were observed during test period.	
830.6319	Miscibility		N/A		
830.6320	Corrosion characteristics	491020-04	A	The commercial containers did not show any signs of corrosion when the test substance was stored for one year under warehouse conditions.	
830.7000	pH	491020-03	A	4.36 at 25 °C	
830.7050	UV/Visible absorption	491020-04	A	Medium	λ_{\max} (nm) Molar Absorption
				Acidic	289 0.0948
				Neutral	286 0.0978
				Basic	286 0.1023
830.7100	Viscosity		N/A		
830.7200	Melting point	491020-03	A	146°C (range of 145°C -147°C)	
830.7220	Boiling point		N/A	Product is a solid	
830.7300	Density	491020-03	A	0.55 g/cc (34.33 lbs/gal) at 22°C	
830.7370	Dissociation constants in water (DC)	Data matrix (4-10-13)	W	Data requirement waived per the Rodenticide Cluster RED	
830.7550	Partition coefficient	491020-03	A	$P_{o/w}$ = 822; Log $P_{o/w}$ = 2.91	
830.7840	Water solubility	491020-03	A	1.57 g/L @ 25°C; almost insoluble in water	
830.7950	Vapor pressure	Literature Citation*	A	1.37×10^{-5} mPa at 25°C	
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers					

*Tomlin Pesticide Manual 11th Edition, British Crop Protection Council, 1997.

{Front Panel}

Diphacinone Technical

A Rodenticide Only for Formulation into Registered Products

Active Ingredient:

Diphacinone (CAS No. 82-66-6)	98.8%
Other Ingredients	1.2%
Total	100.0%

Keep Out of Reach of Children



DANGER POISON

First Aid

If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in Eyes:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1.800.858.7378, seven days a week, 6:30 am-4:30 pm Pacific Time (NPIC website: www.npic.orst.edu).

Note to Physician or Veterinarian: Contains the anticoagulant Diphacinone. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin K-1.

{Note: The first aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

See side [back] panel[s] for additional Precautionary Statements

EPA Reg. No. 72500-__ EPA Est. _____

Net Wt. _____ lbs.
{5 to 200 pounds}
[2.27 kg to 90.72 kg]